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December 13, 2016

VIA ECF

Honorable Claire C. Cecchi,
United States District Court for the District of New Jersey
Martin Luther King, Jr. Federal Building & U.S. Courthouse
50 Walnut Street
Newark, New Jersey 07102

Re: *In re Biogen '755 Patent Litigation*, Civil Action No. 10-2734 (CCC) (JBC)

Dear Judge Cecchi,

At the November 22, 2016 hearing, the Court requested that the parties inform the Court by December 13 whether Bayer and Biogen have resolved Biogen's pending motion to strike (ECF No. 457). Ex. K to Declaration of Seth R. Bowers ("Bowers Decl.") at 128. They have not.

Biogen proposed to withdraw its motion to strike in exchange for modifying the case's schedule to allow it to serve an experimental testing report on December 20 and to make its expert available for deposition during the first week of January. Ex. J to Bowers Decl. The existing case schedule, which both the parties and the Court have expressed the desire to maintain, cannot accommodate Biogen's proposal; Bayer does not agree to it, and the Court should not authorize it. While Bayer was willing to grant Biogen a reasonable extension to the expert report deadlines to enable Biogen to conduct experimental testing, Biogen has now had nearly five months since the report of Bayer's testing expert, Dr. Moore, was served, and Biogen long ago refused Bayer's offer of time for testing. For Biogen to serve a supplemental testing report now would set the schedule back by months and would prejudice Bayer. Dr. Moore already has been deposed in reliance on Biogen's refusal of Bayer's offer of a scheduling accommodation, and in any event, the schedule Biogen proposes is unworkable.

Biogen could have, and should have, conducted any further testing and served any reports prior to expert depositions. Biogen instead chose to roll the dice by filing a motion to strike on the basis that it was prejudiced because testing would take more than a year. ECF No. 457-1 at 14. Apparently, Biogen now believes that gamble was a poor bet. But the Court should not upend the case schedule to relieve Biogen of the consequences of its wagering. Biogen's proposed delay of the schedule to accommodate new testing, which inevitably will delay the adjudication of Bayer's anticipation argument at summary judgment and/or trial, is especially

unwarranted in view of Biogen's actions over the last six months, including its representation to Bayer and repeated suggestions to the Court that it would not and could not perform testing.

A. July – September: Bayer Facilitates Biogen's Efforts To Perform Testing

Bayer served the expert report of Dr. Gordon Moore on July 29, 2016, along with copies of the laboratory notebooks supporting the testing that Dr. Moore supervised. At that time, Bayer indicated that the original materials were available for Biogen's inspection at its convenience.

On August 16, Biogen asked to inspect original materials underlying Dr. Moore's report. Ex. A to Bowers Decl. Bayer promptly made the necessary arrangements, and on August 19, two of Biogen's attorneys and Biogen's testing expert, Dr. Pastor Couceyro, had all of the time they wished to inspect and scan Dr. Moore's experimental records.

Meanwhile, on August 18, Biogen wrote to Bayer objecting to Dr. Moore's report and requesting to meet-and-confer about the issue. Ex. B to Bowers Decl. The parties then had a series of calls, over the course of which Biogen suggested that it wished to perform experimental testing and requested samples of the biological materials that Dr. Moore had tested. *E.g.*, Ex. C to Bowers Decl. Over the course of these discussions, Bayer explained that it was "willing to discuss an extension of the deadline for Biogen to serve reports regarding testing responsive to Dr. Moore's report" and asked Biogen to explain how much time it believed it would need. *Id.* Bayer also agreed to provide samples of the DNA tested in Dr. Moore's experiments, and, on September 1, 2016, Bayer asked Biogen where it would like the samples shipped. Ex. D to Bowers Decl.

Under the then-existing schedule, the deadline for rebuttal expert reports was September 13, 2016. In order to accommodate Biogen's desire for additional time to respond to Dr. Moore's report, including by performing its own testing, the parties negotiated a stipulation to change the deadline for rebuttal reports from September 13 to September 27 (the ensuing deadlines were extended and, in order to maintain the trial date, severely compressed). The stipulation, submitted September 9 and entered September 12, recognized that "Biogen has contended that it may need additional time (including time beyond the agreed-upon extension requested herein) **to perform testing or other analysis in response to Dr. Moore's report**, but has not determined how much additional time it might need, and Bayer has expressed a willingness to negotiate such a further extension." ECF No. 447 at 1 (emphasis supplied).

About two weeks later, Biogen identified a laboratory to which it would like the samples shipped, and Bayer promptly sent the samples to Charles River Laboratories on behalf of Biogen on September 13, 2016. Ex. E to Bowers Decl. At that time, Biogen still had not proposed a deadline for its response to Dr. Moore's report—including by testing or other analysis—so Bayer asked Biogen to propose a deadline of its own choosing. On September 15, Bayer again requested that Biogen propose a deadline for its response to Dr. Moore's report. Ex. F to Bowers Decl. Following a series of phone conversations during which Biogen explained that it was having difficulties with Charles River Laboratories but was discussing performing testing with other labs it had identified, on September 22, Biogen conveyed to Bayer that "**Biogen is no longer interested in agreeing to an extension to perform experimental testing**, and that it will instead move to strike Dr. Moore's expert report." Ex. G to Bowers Decl. (emphasis supplied). At that time, approximately three months ago, Biogen was discussing the performance of experiments with laboratories other than Charles River, and decided and represented unequivocally that it would not seek an extension to perform experimental testing. After Bayer

relied on that representation (as discussed below), after Biogen attempted to strike Dr. Moore's report on the basis of its representation that it would not (and, according to Biogen, could not) perform responsive testing, and after the hearing before the Court, Biogen now seeks to avoid the consequences of its decision, to the great prejudice of Bayer.

B. September – November: Biogen Proceeds with Expert Discovery and Motions Practice

Given Biogen's stated intent *not* to pursue testing, the case proceeded accordingly and in reliance on Biogen's statement.

Most importantly, on the basis of Biogen's representation, the parties agreed to a schedule to finish serving expert reports and to proceed with expert depositions, so as to preserve the September 2017 trial date. Thus, Bayer consented to another extension for Biogen to serve its report responsive to Dr. Moore's report, and Biogen eventually served such a report from Dr. Couceyro on September 29. Because of Biogen's delay in producing materials underlying Dr. Couceyro's opening report, the parties further agreed to a deadline of October 26 for Bayer to serve reports responding to Dr. Couceyro's reports. *See* Ex. H. to Bowers Decl. (noting that "Bayer can include in its response to the Couceyro's [sic] report whatever it wants to say in reply to Biogen's response to the Moore report"). At that time, Bayer served a second report from Dr. Moore.

Having completed expert reports, the parties scheduled expert depositions. As Biogen noted during the hearing, the case involves so many expert depositions that Biogen's counsel has "lost track." Ex. K to Bowers Decl. at 100-101. (Reports from 35 different experts have been served.) Bayer notified Biogen that Dr. Moore would be available for deposition on November 11, a date that Bayer never would have offered had Biogen ever suggested that there was any possibility that it would serve a further response to Dr. Moore's reports. For its part, Biogen never suggested that it would seek to serve an additional response to Dr. Moore's report, and it deposed Dr. Moore on November 11 for a full day, adjourning the deposition at 7:09 pm.

Because Biogen had stated it would not pursue testing, Bayer asked Biogen to return the DNA samples that Bayer had produced to it. Ex. H to Bowers Decl. Biogen promptly did so. Ex. I to Bowers Decl.

Meanwhile, the parties agreed to a briefing schedule for Biogen's motion to strike. ECF No. 455. In that briefing, Biogen suggested that it was prejudiced by being unable to find a laboratory that could replicate Dr. Moore's experiments, explaining that Charles River Laboratories would not perform the experiments, but declining to advise whether Biogen had contacted or even retained other labs. *See* ECF No. 457-1 at 14.

Noting the careful (and potentially misleading) phrasing of Biogen's motion, Bayer observed in opposition that Biogen "does not represent that it could not find a suitable lab." ECF No. 460 at 14. Despite this invitation to clarify the record and admit to the Court that it had found another lab and therefore had not suffered the prejudice its principal brief suggested, Biogen's reply brief was absolutely silent as to whether it had retained other labs. *See* ECF No. 463.

The Court held a hearing on Biogen's motion to strike on November 22. During the hearing, Biogen perpetuated the illusion that it had been prejudiced and could not perform its

own testing as its basis for striking Dr. Moore's report. Biogen went so far as to avoid answering a point-blank question from the Court:

THE COURT: Are you still interested in looking for another lab?

MR. GROOMBRIDGE: I think, your Honor, that we would be interested in seeing what -- is there some series of steps that we can do that we think puts us on an equal footing here, or as far as possible, with Bayer. And I mean, one way forward would be for us to think about that and then come back in the first instance I suspect to counsel for Bayer and ultimately to the Court and say, how about if we do this.

Ex. K to Bowers Decl. at 124-125. A more forthright answer would have advised the Court that Biogen already had retained at least one other lab, but that Biogen had represented that it would not perform testing in response to Dr. Moore's report, that Bayer and the Court relied on that representation in negotiating and entering a schedule that preserves the trial date, that Bayer had relied on that statement by not arranging for any analysis or responsive testing, and that Bayer's expert already had been deposed. Biogen neither acknowledged its ongoing testing plans that refuted its sole basis for prejudice nor suggested that it intended to dishonor and abrogate the representation on which Bayer had relied.

Rather, in an effort to preserve its options, Biogen obfuscated. Bayer remarked on Biogen's position, observing that "Biogen has not told this Court and it has not told us that it failed to find a laboratory that could conduct the hybridization experiment[.]" Ex. K to Bowers Decl. at 126. Biogen again declined to clarify whether it had retained such labs. Instead, the hearing on Biogen's motion to strike concluded with the following exchange:

THE COURT: Well, since everyone is here, I know you suggested you might take some time to ponder this, but is there anything else you would suggest as a means of moving forward?

MR. GROOMBRIDGE: *I don't think there's anything I would suggest right now*, your Honor, but I think it may be productive for counsel to discuss this and see if we can arrive at a way of doing this. We certainly don't want the schedule disrupted.

Ex. K to Bowers Decl. at 127 (emphasis added). Again, given the chance at the hearing to explain what it would propose, Biogen chose to preserve its prejudice argument and demurred.

C. December: Biogen Requests a Do-Over

Following the November 22 hearing, Bayer heard nothing from Biogen until December 6. At that time, Biogen proposed to Bayer that it would withdraw its motion to strike if Bayer agreed, *inter alia*, to allow Biogen to serve on December 20, 2016, a supplemental expert report from Dr. Pastor Couceyro, the same expert Biogen has had working on the case for years and who had already served Biogen's agreed-upon rebuttal to Dr. Moore's report in September. Ex. J to Bowers Decl.

Bayer followed up with Biogen to understand the subject matter of the report Biogen was requesting leave to serve. Only after this follow-up questioning did Biogen reveal that its

proposed report involved additional experimental testing. Bayer pressed for more detail a second time—asking Biogen what testing it proposed to do—and received on December 10 a document entitled “Testing Protocol” that purports to describe the methodology (but not the results) of the experiments Biogen has performed. Biogen’s new “Testing Protocol” failed to describe what pieces of DNA were being analyzed, which is particularly significant because Biogen returned the DNA samples that Bayer had provided in September without testing them. That is, whatever Biogen has tested, it is not the materials Bayer supplied; if the supplemental testing report were allowed, Bayer would need an opportunity to analyze what Biogen tested instead.

Bayer declined Biogen’s proposal and suggested that the parties submit separate letters apprising the Court of the status.

* * *

The timeline set forth above makes clear that Biogen has tried to manipulate the process so as to prejudice Bayer. As Bayer previously explained, the experiments at issue take one to two weeks to perform *once a lab has the necessary DNA in hand*, ECF No. 460 at 14. Because Biogen returned Bayer’s DNA samples back in September, Biogen must have created the DNA samples it tested. The notion that Biogen retained a testing laboratory and performed all of this sample preparation and testing following the hearing on November 22 simply strains credulity. Even if Biogen somehow retained a lab, began and completed further testing using newly created DNA samples, and decided to serve a supplemental report in the short interval over Thanksgiving and following the hearing, its apparent ability to do so belies its protestations of prejudice, and leads inexorably to the question of why Biogen did not conduct this testing when the schedule contemplated it, during the summer. Later, when Biogen apparently already was working with other labs, it represented it would forgo testing in response to Dr. Moore’s report, served its response to Dr. Moore’s report, received Dr. Moore’s rebuttal report on the subject of testing, and deposed Dr. Moore. That clock cannot be unwound. Instead of performing testing during the prescribed time or even accepting a reasonable accommodation back when it would not have been disruptive (as Bayer offered), Biogen chose to suggest repeatedly to the Court that it could not perform testing and was prejudiced, moved to strike Bayer’s entire invalidity defense on that basis, and then evaded questions about whether it still sought to conduct its own testing.

Setting aside the propriety of Biogen’s behavior, the schedule Biogen now proposes is untenable. Biogen wants to serve a new testing report from Dr. Couceyro on December 20. Bayer’s expert, Dr. Moore, is scheduled to be out of the country during the Christmas holidays, until January 10, followed by another extended trip abroad. Biogen has proposed a deposition the first week of January, leaving no time in the schedule for Bayer to consult with its expert before Dr. Couceyro could be deposed concerning his report. Biogen has also failed to identify the DNA samples that it is using in its tests or how they were prepared. There is simply no time in the schedule for Bayer to verify experimentally that the samples Biogen tested are what they purport to be or to perform any other analysis. The expert deposition schedule was already extended into 2017, and the ensuing deadlines for summary judgment compressed, in response to Biogen’s request for additional time to serve responsive expert reports. ECF No. 447. Bayer’s summary judgment motion is due February 3. The expert deposition schedule cannot be extended again without delaying Bayer’s trial date (Serono is not relying on Dr. Moore’s testing).

After receiving Dr. Moore’s testing report, Biogen had and used two full months to respond and more than three months to perform analysis before deposing Dr. Moore. Providing Bayer a commensurate amount of time to respond would result in Dr. Couceyro being deposed in

early April, after summary judgment briefing has been completed under the current schedule. Rather than provide Bayer a fair opportunity to respond, which the schedule does not permit without adjournment of Bayer's trial date, Biogen proposes that Bayer have two weeks over the Christmas holiday (when its expert is away) to analyze its testing of new materials and to take discovery. Ex. J to Bowers Decl. And by springing this report on Bayer after Dr. Moore's deposition, Biogen has deprived Bayer of the opportunity to have its expert comment on Biogen's report within the expert discovery period.

In sum, Biogen had a decision in the summer of 2016: include experimental testing in its response to Dr. Moore's report or file a motion to strike on the basis that it could not perform such testing. It chose the latter and represented that it would not perform additional responsive testing. The parties, including Bayer, relied on that representation to reach agreement regarding the timing of expert reports and discovery, and they proceeded accordingly. Further, to maintain the illusion of "prejudice," Biogen postponed and/or concealed its efforts to perform testing. Apparently having concluded that its motion to strike was baseless, Biogen is now asking to submit an untimely response on the merits that the schedule prevents Bayer from assessing fairly. Biogen's motion to strike should be denied for the reasons discussed at the hearing, and Biogen's belated request to modify the schedule to serve a new expert report should be denied as well.

Respectfully submitted,

GREENBAUM ROWE SMITH AND DAVIS LLP

/s/ Robert M. Goodman

ROBERT M. GOODMAN

cc: Counsel of Record (via ECF)